



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 26, 2015

Foshan United Medical Technologies LTD
% Ms. Marcia Palma
NAMSA
4050 Olson Memorial Highway, Suite 450
Minneapolis, Minnesota 55422

Re: K143124

Trade/Device Name: KA01 Chitosan Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 30, 2014
Received: October 31, 2014

Dear Ms. Palma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K143124

Device Name

KA01 Chitosan Wound Dressing

Indications for Use (Describe)

The KA01 Chitosan Wound Dressing is indicated for the management of moderately to heavily exuding chronic wounds and acute wounds. Under medical supervision the KA01 Chitosan Wound Dressing may be used for the management of:

- Pressure sores
- Diabetic ulcers
- Leg ulcers
- Donor sites and Graft sites
- Surgical wounds
- Skin abrasions and lacerations
- 1st and 2nd degree burns
- Trauma wounds

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Indications for Use

510(k) Number (if known)
K143124

Device Name

KA01 Chitosan Wound Dressing

Indications for Use (Describe)

The KA01 Chitosan Wound Dressing may be used for the management of:

- Minor cuts
- Minor scalds and 1st degree burns
- Abrasions
- Lacerations

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary

1. Submission Sponsor

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3. Date Prepared

January 22, 2015

4. Device Identification

Trade/Proprietary Name:	KA01 Chitosan Wound Dressing
Common/Usual Name:	Dressing, Wound, Drug
Classification Name:	Unclassified
Classification Regulation:	Unclassified
Product Code:	FRO
Device Class:	Unclassified
Classification Panel:	General and Plastic Surgery

5. Predicate Devices

Primary: K070175	MedTrade Products Aquanova Super-Absorbent Dressing
Secondary: K063271	Convatec Aquacel Hydrofibre Wound Dressing

6. Device Description

The KA01 Chitosan Wound Dressing is a sterile non-woven chitosan dressing comprising 100% chitosan fibers. The KA01 Chitosan Wound Dressing is a highly absorbent, conformable and wet integral. As wound exudate is absorbed the chitosan forms a gel, which assists in maintaining a moist environment for optimal wound healing, aids autolytic debridement, and allows intact removal.

The KA01 Chitosan Wound Dressing is intended for use as a primary dressing on a variety of chronic and acute wounds. It is intended to be secured with a semi permeable adhesive secondary dressing and to remain in place up to 7 days depending on the level of exudate. Dressings are individually packed in paper/poly pouches and terminally sterilized to achieve a SAL 10^{-6} . A range of dressing sizes between 25cm² and 220cm² is available.

Flat Dressing Sizes:

5 x 5cm, 7.5 x 12cm, 10 x 10cm,
10 x 12cm, 10 x 20 cm

Flat Rope Dressing Sizes:

1.5 x 45cm, 2.5x45 cm, 3 x 45cm,
3 x 30cm, 4x10 cm, 4x20 cm, 4x30 cm

7. Indication for Use

Rx:

The KA01 Chitosan Wound Dressing is indicated for the management of moderately to heavily exuding chronic wounds and acute wounds. Under medical supervision the KA01 Chitosan Wound Dressing may be used for management of:

- Pressure sores
- Diabetic ulcers
- Leg ulcers
- Donor sites and graft sites
- Surgical wounds
- Skin abrasions and lacerations
- 1st and 2nd degree burns
- Trauma wounds

OTC:

The KA01 Chitosan Wound Dressing may be used for the management of:

- Minor cuts
- Minor scalds and 1st degree burns
- Abrasions
- Lacerations

8. Comparison to Predicates

The intended use, device design, mechanism of action, material and performance testing of KA01 Chitosan Wound Dressing, as designed and manufactured, are determined to be substantially equivalent to the referenced predicate devices. The differences between the KA01 Chitosan Wound Dressing and the predicate devices do not raise any questions regarding its safety and effectiveness.

Comparison to Predicate Devices			
Parameter	KA01 Chitosan Wound Dressings	Primary: Aquanova Super-Absorbent Dressing	Secondary: Aquacel Dressing
510(k) Number Decision Date	TBD	K070175	K063271
Manufacturer	Foshan United Medical Technologies Ltd	MedTrade Products	Convatec
Classification	Unclassified	Same	Class I
Product Code	FRO	Same	NAC
Regulation Number and Name	Unclassified	Same	878.4018 Hydrophilic wound dressing
Indications for Use	<p>Rx: The KA01 Chitosan Wound Dressing is indicated for the management of moderately to heavily exuding chronic wounds and acute wounds. Under medical supervision the KA01 Chitosan Wound Dressing may be used for the management of:</p> <ul style="list-style-type: none"> • Pressure sores • Diabetic ulcers • Leg ulcers • Donor sites and Graft sites • Surgical wounds • Skin abrasions and lacerations • 1st and 2nd degree burns • Trauma wounds <p>OTC: The KA01 Chitosan Wound Dressing may be used for the management of:</p> <ul style="list-style-type: none"> • Minor cuts • Minor scalds and 1st degree burns • Abrasions • Lacerations 	<p>Under the supervision of a healthcare professional AQUANOVA may be used for wounds such as leg ulcers (Stages I-IV), diabetic ulcers, surgical wounds (post-operative, donor sites, dermatological), burns (first and second degree) and the management of surgical or traumatic wounds which have been left to heal by secondary intention. AQUANOVA may also be used for the local management of wounds that are prone to bleeding such as wounds that have been surgically debrided, donor sites, and traumatic</p>	<p>Under the supervision of a health care professional, Aquacel may be used for management of:</p> <ul style="list-style-type: none"> - leg ulcers, pressure ulcers (Stage II-IV) and diabetic ulcers - surgical wounds (post-operative, donor sites, dermatological) - second degree burns - surgical or traumatic wounds left to heal by secondary intention - local management of wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided, donor sites, and traumatic wounds - the management of painful wounds

Comparison to Predicate Devices			
Parameter	KA01 Chitosan Wound Dressings	Primary: Aquanova Super-Absorbent Dressing	Secondary: Aquacel Dressing
		wounds. AQUANOVA can also be used in the control of minor bleeding. AQUANOVA Super-Absorbent OTC is indicated for minor burns, superficial cuts, lacerations and abrasions, and minor irritations of the skin.	For Over the Counter Use: Aquacel Hydrofiber Wound Dressing may be used for: -abrasions -lacerations -minor cuts -minor scalds and burns
Intended Use	Intended for prescription use in the management of chronic wounds, postoperative wounds and traumatic wounds. Also intended for over-the-counter use for minor cuts, burns, abrasions and lacerations.	Same	Same
Device Design	Absorbable, single layer, needle punched non-woven pad or ribbon dressing that can be cut or folded	Same	Same
Material	100% Chitosan fibers	Chitosan, chitosan derivatives, and structural material	Hydrocolloid fibers (sodium carboxymethyl-cellulose)
Mechanism of Action	Conformable, highly absorbent dressing that forms a soft clear gel on contact with wound exudate which maintains a moist environment for optimal wound healing, provides patient comfort and allows painless intact removal.	Same	Same
Sterility	SAL 10^{-6}	Same	Same
Single Use	Yes	Same	Same
Biocompatible	Yes	Same	Same

9. Functional and Safety Testing

To verify that device design met its functional performance and safety requirements,

representative samples of the device underwent testing including bench testing (absorbency, gel absorbency retention, moisture content, pH), viral inactivation testing, biocompatibility testing (cytotoxicity, irritation, sensitization, systemic toxicity), packaging testing (pouch seal and transportation), sterilization validation testing, and shelf life stability testing (accelerated aged and real time).

10. Conclusion

Foshan United Medical Technologies Ltd considers the KA01 Chitosan Wound Dressing to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in intended use, design, mechanisms of action, technology and materials.